

Amendments to the Drawings:

The attached sheet of drawings includes changes to Figure 1A. This sheet, which includes Figure 1A, replaces the original sheet including Figure 1A.

Attachment: Replacement Sheet

REMARKS

Claims 66-71, 80-90, 92-111, 121-124, and 126-131 are pending in this application. Claims 130 and 131 are new. Claims 1-65, 72-79, 91, 112-120 and 125 are canceled.

The Examiner objected to Figure 1A. Figure 1A has been amended to address the Examiner's concerns and one sheet of drawings is presented herewith for approval.

The Examiner rejected claims 66, 71, 80, 85, 86, 88-90, 92, 94, 96, 99-102, 109, 110, and 127-129 under 35 U.S.C. Section 102(b) as being anticipated by U.S. Patent No. 4,471,776 issued to Cox. The Examiner also rejected claim 83 under 35 U.S.C. Section 103(a) as being obvious over Cox in view of U.S. Patent No. 6,743,234 issued to Burkus, et al.; claims 67-70, 84, and 93 as being obvious over Cox in view of U.S. Patent No. 4,848,331 issued to Northway-Meyer; claims 81, 82, 87, 97, 98, 111, 121, and 123 as being obvious over Cox in view of U.S. Patent No. 5,546,937 issued to Stuart; claims 95 and 103-108 as being obvious over Cox in view of U.S. Patent No. 5,873,362 issued to Parker; claims 122 and 126 as being obvious over Cox in view of U.S. Patent No. 5,250,033 issued to Evans, et al.; and claim 124 as being obvious over Cox in view of Stuart as applied to claim 123 and further in view of Evans, et al. Applicant respectfully traverses the Examiner's rejections.

As an initial matter, Cox is not an anticipating reference and is an inappropriate primary reference for obviousness purposes. Cox is directed to a static tracheostomy tube with an obturator inside to give the tracheostomy tube shape. The tracheostomy tube and the obturator are positioned in a patient's trachea at the same time. Assuming, *arguendo*, that Cox discloses intubation as opposed to tracheostomy, merely showing that a reference discloses a concept does not show that the reference anticipates the claims. See *Panduit Corp. v. Dennison Mfg. Co.*, 774 F.2d 1082, 1101 (Fed. Cir. 1985). To constitute anticipation, all the claimed elements must be found in exactly the same situation and united in the same way to perform the identical function in a single unit of prior art. See *General Elect. Co. v. Nintendo Co., Ltd.*, 179 F.3d 1350, 1356-57 (Fed. Cir. 1999). As discussed below in more detail with regard to features of specific claims, Cox is not an anticipating reference because it does not disclose all of the claimed elements in the exact same situation and united in the same way to perform the same function. Similarly, with regard to obviousness, Cox is not an appropriate primary reference

because Cox teaches away from the present invention, which is directed to an intubation device and method where a placement device is introduced into patient's trachea and the intubation tube is slid along the placement device into position in the patient's trachea.

The Examiner points to the malleable main shaft means 68 of the obturator 18 of Figure 8 of Cox as an intubation placement device, to the flexible tube means 12 as the intubation tube having a distal end and a proximal end, and to the grasping knob 70 as a stopper. The malleable main shaft means of Cox is a metal stylet and Cox describes the insertion process as follows:

The curved configuration of the flexible tube means 12 is obtained by inserting the obturator 18 into the flexible tube means 12 and then bending the two elements to the desired curve configuration for insertion into the trachea 42 of patient 40. The curved shape is maintained by the bent obturator 18 which is malleable to permit bending, but is rigid enough to maintain the curved configuration.

After the flexible tube means 12 of the tracheostomy tube 10 is inserted into the trachea and the precision cuff means 14 is inflated as hereinafter described, the obturator 18 is removed by withdrawing the obturator 18 from the flexible tube means 12.

See Cox at Column 4, line 59 to Column 5, line 3. There is no indication in Cox that obturator 18 is introduced before the tracheostomy tube 10. There also is no indication that the guide nub 72 of the obturator 18 is configured to be introduced through a set of vocal cords. Instead, it is configured to facilitate insertion of the obturator 18 into the internal passageway 66 of the flexible tube means 12. The figures of Cox appear to show the obturator 18 is constrained by a distal end of the flexible tube means 12, which is consistent with the insertion of the obturator 18 and flexible tube means 12 at the same time and inconsistent with the obturator 18 being introduced through a set of vocal cords or detecting the cartilaginous rings, and the tracheostomy tube 10 subsequently being slid along the obturator so that it follows the distal end of the obturator 18 through the patient's trachea. Moreover, there is no indication that the malleable main shaft 68 of the obturator 18 extends out of a distal end of the flexible tube means 12. The guide nub 72 is not a bendable distal end of the obturator 18. The grasping knob 70 is not a stopper. The grasping knob 70 is used to extract the obturator 18 from the tracheostomy tube 10. The grasping knob does not removably secure the obturator 18 to the flexible tube means 12.

Further, there is no indication the obturator can be slid with respect to the grasping knob. In contrast, a stopper may be slid into position on a placement device, and then the stopper may removable secure the placement device to an intubation tube.

Turning to the language of the claims, independent claim 66 recites, “[a] method comprising: removably securing a proximal end of an intubation-tube placement device to a proximal end of an intubation tube with a stopper such that the placement device extends through the intubation tube and a tactile accentuator at a distal end of the placement device extends out of a distal end of the intubation tube; inserting the distal end of the intubation-tube placement device into a patient's oral cavity; detecting cartilaginous rings of a trachea via the tactile-accentuator; forcing the distal end of the intubation-tube placement device through the patient's vocal cords; and axially sliding the intubation tube along the intubation-tube placement device such that the intubation tube follows the distal end of the intubation-tube placement device through the patient's vocal cords.” The Examiner contends the recited method is inherent in Cox, pointing to the flexible tube means 12, the obturator 18 and the malleable main shaft 68, and citing to column 6, lines 39-45. The cited portion of Cox describes the guide nub 72 as facilitating the insertion of the obturator 18 into the internal passageway 66 of the flexible tube means 12. There is no suggestion that the guide nub 72 is a tactile accentuator or that it detects cartilaginous rings, and this is not inherent merely because a portion of the guide nub 72 is illustrated as extending a short distance out of the flexible tube means. There is no indication the guide nub 72 comprises flexible materials or flaps that accentuate contact with the cartilaginous rings or that the guide nub 72 in any way assists the caregiver in discerning contact with the cartilaginous rings of the trachea. In fact, there is no suggestion that the guide nub 72 ever makes any contact with any tissue in the patient. Thus, the guide nub 72 is not analogous to the tactile accentuator. Further, where the obturator 18 and the flexible tube means 12 are inserted into the trachea at the same time, the flexible tube means is not axially slid along the obturator such that the flexible tube means follows the distal end of the intubation-tube placement device through the patient's vocal cords. In addition, the grasping knob 70 does not secure the obturator 18 to the tracheostomy tube 10. A method is not inherent merely because a reference could be modified to perform the recited method. To the extent the Examiner continues to contend the recited method is inherent, Applicant respectfully requests citation to supporting evidence. The Examiner does not contend that the missing teachings are disclosed by Burkus, Northway-

Meyer, Stuart, Parker or Evans. Accordingly, claim 66 is not anticipated or rendered obvious by Cox, alone or in combination with Burkus, Northway-Meyer, Stuart, Parker and Evans. Claims 67-71, 126, 128, 129 and 130 depend from claim 66 and are allowable at least by virtue of their dependencies.

Independent claim 80 recites, “[a]n intubation device, comprising: an intubation placement device having a bendable distal end configured to be introduced through a set of vocal cords; an intubation tube having a distal and a proximal end; and a stopper configured to removably secure a proximal end of the placement device to a proximal end of the intubation tube with the placement device extending inside the intubation tube and the distal end of the placement device extending out of the distal end of the intubation tube.” Figure 8 of Cox does not disclose an intubation placement device configured to be introduced through a set of vocal cords with *a bendable distal end extending out of the intubation tube, or a stopper configured to removably secure* the placement device to an intubation tube, as recited. Instead, Figure 8 of Cox shows a tracheostomy tube 10 in a final position in a patient with a guide nub 72 of an obturator 18 partially extending out of the tracheostomy tube 10. There is no indication that the guide nub 72 is a bendable distal end of the obturator 18, and no indication that the grasping knob 70 secures a proximal end of obturator 18 to the tracheostomy tube 10 to the tracheostomy tube 10. The Examiner does not contend that the missing teachings are disclosed by Burkus, Northway-Meyer, Stuart, Parker or Evans. Accordingly, claim 80 is not anticipated or rendered obvious by Cox, alone or in combination with Burkus, Northway-Meyer, Stuart, Parker and Evans. Claims 81-89, 123, 124, 127 and 131 depend from claim 80 and are allowable at least by virtue of their dependencies.

Independent claim 90 recites, “[a] method of intubating a patient, comprising: removably securing a proximal portion of a endotracheal placement device to a proximal end of an intubation tube with a stopper such that the endotracheal placement device extends through the intubation tube and a bendable distal portion of the endotracheal placement device extends out through a distal end of the intubation tube; subsequently guiding the distal portion of the endotracheal placement device through the patient’s vocal cords; guiding the intubation tube through the patient’s vocal cords such that the distal end of the intubation tube follows the distal portion of the endotracheal placement device through the patient’s vocal cords; and subsequently pulling the endotracheal placement device out of the intubation tube, leaving the intubation tube

in position in the patient.” As discussed above, Cox does not teach *removable securing* a proximal portion of an endotracheal placement device to a proximal end of an intubation tube *with a stopper* such that the endotracheal placement device extends through the intubation tube and a *bendable distal portion* of the endotracheal placement device *extends out through a distal end* of the intubation tube, guiding the distal portion of an endotracheal placement device through the patient’s vocal cord and guiding the intubation tube through the patients vocal cords. The grasping knob 70 is not a stopper and does not removable secure the obturator to the tracheostomy tube 10. The guide nub 72 is not a bendable distal end of the obturator 18. The Examiner does not contend the missing teachings are disclosed by Burkus, Northway-Meyer, Stuart, Parker or Evans. Accordingly, claim 90 is not anticipated or rendered obvious by Cox, alone or in combination with Burkus, Northway-Meyer, Stuart, Parker and Evans. Claims 92-95 and 122 depend from claim 90 and are allowable at least by virtue of their dependencies.

Independent claim 96 recites, “[an] intubation device, comprising: an intubation tube having a distal end and a proximal end; a endotracheal placement device having a semi-rigid distal end configured to pass through vocal cords and into a trachea; and a stopper configured to removably secure a proximal end of the endotracheal placement device to the proximal end of the intubation tube with the placement device extending through the intubation tube and the distal end of the endotracheal placement device extending out of the distal end of the intubation tube.” As noted above, Cox does not teach a stopper configured to removable secure an endotracheal placement device to an intubation tube with a semi-rigid distal end extending out of the intubation tube. The Examiner does not contend the missing teachings are disclosed by Burkus, Northway-Meyer, Stuart, Parker or Evans. Accordingly, claim 96 is not anticipated or rendered obvious by Cox, alone or in combination with Burkus, Northway-Meyer, Stuart, Parker and Evans. Claims 97-108 and 121 depend from claim 96 and are allowable at least by virtue of their dependencies.

Independent claim 109 recites, “[an] intubation device, comprising: means for introducing the intubation device through vocal cords; and a *stopper configured to secure* a proximal end of an intubation tube to a proximal end of the means for introducing with the means for introducing extending through the intubation tube and a distal end of the means for introducing extending out of a distal end of the intubation tube.” As discussed above, Cox does not disclose a stopper configured to secure a proximal end of an intubation tube to a proximal

end of the means for introducing with the means for introducing extending through the intubation tube and a distal end of the means for introducing extending out of a distal end of the intubation tube. The grasping knob 70 of Cox is not a stopper and does not secure the obturator to the tracheostomy tube. The Examiner does not contend the missing teachings are disclosed by Burkus, Northway-Meyer, Stuart, Parker or Evans. Accordingly, claim 109 is not anticipated or rendered obvious by Cox, alone or in combination with Burkus, Northway-Meyer, Stuart, Parker and Evans. Claims 110 and 111 depend from claim 109 and are allowable at least by virtue of their dependencies.

As noted above, all of the dependent claims are allowable at least by virtue of their dependencies. However, Applicant respectfully offers the following additional comments regarding the allowability of the dependent claims.

With regard to dependent claims 70, 88, 89, 94, 130 and 131 as discussed above there is no indication in Cox that the guide nub 72 is a tactile accentuator or that it detects cartilaginous rings, and this is not inherent merely because a portion of the guide nub 72 is illustrated as extending a short distance out of the flexible tube means. There is no suggestion in Cox that the guide nub 72 ever makes any contact with any tissue in the patient. Thus, claims 89 and 94 are not anticipated or rendered obvious by Cox for at least the additional reason that Cox does not disclose a tactile accentuator as claimed and claims 70 and 88 are not anticipated or rendered obvious by Cox for at least the additional reason that Cox does not disclose an anti-perforation device as claimed.

Dependent claim 92 recites "twisting the endotracheal placement device and the endotracheal tube in opposite directions." Dependent claim 128 recites, "inserting the placement device into a hole in the stopper and inserting the stopper into the intubation tube; and inserting the distal end of the intubation-tube placement device into the patient's oral cavity comprises manipulating the intubation-tube placement device by manipulating the stopper." Dependent claim 129 recites "using mechanical friction to hold the placement device in position in the intubation tube." The Examiner points to Figures 1, 2 and 7 and Column 6, lines 28-38 contends that connector 64 partially receives the grasping knob 70. The Examiner does not explain how this anticipates or renders obvious the recited features. Assuming *arguendo* that the obturator 18 and the tracheostomy tube 10 of Cox correspond to the claimed configuration of a placement device and intubation tube (they do not for at least the reasons set forth above with regard to the

corresponding independent claims), Figures 1, 2 and 7 do not inherently show (or even suggest) twisting the obturator and the flexible tube means in opposite directions, that the grasping knob 70 is a stopper with a hole, or that the grasping knob 70 is frictionally received by the connector 64. The cited portion of Cox discusses coupling the tracheostomy tube 10 to a mechanical respirator after the tube is in position and the obturator 18 has been removed. Accordingly, claim 92 is not anticipated or rendered obvious by Cox for at least the additional reason that Cox does not disclose twisting an endotracheal placement device and an endotracheal tube in opposition directions, claim 128 is not anticipated or rendered obvious by Cox for at least the additional reason that Cox does not disclose the claimed stopper, and claim 129 is not anticipated or rendered obvious by Cox for at least the additional reason that Cox does not disclose using mechanical friction to hold a placement device in position in an intubation tube.

With regard to dependent claim 83, the Examiner cites Burkus and points to the shaft 384 of a disc space distractor 380 that has a hollow interior 387 to reduce weight. The Examiner contends this would motivate one of skill in the art to hollow-out the obturator of Cox. As discussed above, claim 83 is allowable at least by virtue of its dependency. However, Applicant respectfully traverses that one of skill in the art would be motivated to reduce the weight of the obturator of Cox by the distractor of Burkus, and that doing so would somehow teach or suggest the claimed placement device. There is no indication that weight was a problem in Cox or that the obturator of Cox could be hollowed out and still serve its intended purpose of maintaining the flexible curved shape of the flexible tube means 12 of the tracheostomy tube 10. Accordingly, claim 83 is not rendered obvious by Cox in view of Burkus for at least the additional reason that Cox, alone or in combination with Burkus, does not teach, suggest or motivate the claimed placement device.

With regard to dependent claims 67-70, 84 and 93, the Examiner concedes that Cox does not disclose an intubation tube placement device that suctions materials or that includes fiber-optic cables. The Examiner contends that Northway-Meyer provides the motivation to modify the obturator of Cox to include a light source and to modify the obturator of Cox to form a suction tube. The Examiner points to Column 2, lines 15-35 of Northway-Meyer. The cited portion of Northway-Meyer identifies problems with routine laryngoscopy, namely that frequent suctioning of secretions or blood is required and that it is difficult to use a

fiberoptic scope without a ventilating/intubating airway in place. The Examiner does not point to any solutions to these problems provided by Northway-Meyer. Applicant assumes the Examiner is taking about the suction channel plug and opening of Figures 12 and 20 of Northway-Meyer with regard to suctioning and to the separate fiber-optic cable in the lumen of the endotracheal tube with regard to the light source. Northway-Meyer teaches away from the present invention by using a suction channel plug and opening for suctioning materials. See Figures 12 and 20 of Northway-Meyer and the description thereof. Further, there is no suggestion in Northway-Meyer to modify an obturator to include a light source. Modifying the tracheostomy tube of Cox to include the suction channel plug and opening of Northway-Meyer and the separate fiber-optic cable would not achieve the claimed invention. Accordingly, claims 67 and 84 are not rendered obvious over Cox by Northway-Meyer at least for the additional reason that modifying the obturator of Cox to include the fiber-optic cable of Northway-Meyer would not achieve the claimed placement device including a light source, and claims 68-70 and 93 are not rendered obvious over Cox in view of Northway-Meyer for at least the additional reason that modifying the obturator of Cox to include the plug and channel arrangement of Northway-Meyer would render the obturator of Cox inoperative for its intended purpose and would not achieve the claimed placement device forming a suction tube. Applicant notes that claim 70 also recites an anti-perforation device, which as discussed above is not disclosed in Cox and the Examiner does not contend it is disclosed by Northway-Meyer.

With regard to claims 81, 82, 97, 98, 111, 121 and 123, the Examiner points to the grasping knob 70 and the shaft 68 of the obturator 18 of Cox and to the use of a plastic obturator in Stuart. The Examiner contends this combination renders claims 81, 82, 97, 98, 111, 121 and 123 obvious. The Examiner does not discuss the language of the claims.

Claims 81, 97 and 111 recite, "wherein the stopper comprises a rubber stopper having a center hole configured to receive the intubation placement device" (or similar language). There is no indication in Cox that the grasping knob 70 is a stopper, is rubber or that it has a center hole. The portion of Stuart to which the Examiner points does not disclose rubber stoppers. Column 4, lines 6-29 discuss an obturator having flexible portions and do not mention a rubber stopper. Column 6, lines 49-55 discuss materials from which an obturator may be

made, and do not discuss a stopper. Claim 82 depends from claim 81. Accordingly, claims 81, 82 and 97 are not rendered obvious by Cox in view of Stuart for at least the additional reason that Cox in combination with Stuart does not disclose a rubber stopper with a center hole configured to receive a placement device.

Claims 98, 121 and 123 recites, “a detachable portion of the intubation tube” (or similar language). The cited portions of Cox and Stuart do not discuss intubation tubes, let alone an intubation tube having a “detachable portion.” Accordingly, claims 98, 121 and 123 are not rendered obvious over Cox in view of Stuart for at least the additional reason that Cox in combination with Stuart does not disclose an intubation tube having a detachable portion as recited.

With regard to claim 105, the Examiner contends that Parker discloses a tapered end. Claim 105 recites, “the tip of the distal end of the intubation tube is configured to taper to approximately a diameter of the distal end of the endotracheal placement device.” The cited portion of Parker does not disclose an intubation tube that tapers to a diameter approximately equal to a diameter of a placement device.

Claim 122 recites, “wherein pulling the endotracheal placement device out of the intubation tube comprises: breaking a perforated border adjacent to the proximal portion of the intubation tube.” Claim 126 recites, “breaking a perforated border along a portion of the intubation tube.” The Examiner points to the peel-away sheath of Evans of providing the missing teachings of Cox. Modifying the obturator of Cox to have a peel-away sheath would render the tracheostomy tube of Cox unsuitable for its intended purpose. In Cox, the obturator is inside the tracheostomy tube when it is positioned in the patient. If the obturator were peeled away to remove it from the tracheostomy tube, the tracheostomy tube would need to be removed from its position in the patient. Similarly, modifying the tracheostomy tube of Cox to have a peel-away sheath would render Cox unsuitable for its intended purpose, and would not result in removal of the obturator from the tracheostomy tube of Cox while leaving the tracheostomy tube in place in the patient. Accordingly, claims 122 and 126 are not rendered obvious by Cox in view of Evans for at least the additional reason that Cox in combination with Evans does not render obvious the claimed perforated boarder.

Claim 124 depends from claim 123 and recites, "wherein a border of the detachable portion is perforated." The Examiner points to Stuart and Evans as teaching a stopper with a perforated edge. As discussed above, the cited portion of Stuart does not discuss stoppers or perforations. Evans discusses a peel away sheath. Modifying the tracheostomy tube to add a peel away sheath would not result in the claimed invention, and would not facilitate removal of the obturator from the tracheostomy tube. The Examiner also appears to suggest claiming a perforated border in a device claim has no impact on patentability. Applicant respectfully disagrees. Claiming a perforated border is not functional language in a device claim. *See Cole v. Kimberly Clark Corp.*, 102 F.3d 524, 531 (Fed. Cir. 1996) (perforated means recited a structure). Moreover, assuming arguendo that a perforated border was functional language (it is not), functional language in a device claim can have patentable significance.

All of the claims remaining in the application are now clearly allowable.
Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,

SEED Intellectual Property Law Group PLLC



Timothy L. Boller
Registration No. 47,435

TLB:asl

Enclosure:

1 Sheet of Drawings (Figure 1A)
701 Fifth Avenue, Suite 5400
Seattle, Washington 98104
Phone: (206) 622-4900
Fax: (206) 682-6031

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